OMB INFORMATION COLLECTION
SUPPORTING STATEMENT
0910-0336

Current Good Manufacturing Practices for Blood and Blood Components; Notification of Consignees Receiving Blood and Blood Components at Increased Risk for Transmitting HIV Infection

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting an extension of OMB Control No. 0910-0336 and OMB approval of the following information collection requirements in 21 CFR, 606.160, 610.46, 610.47 (Attachment A):

21 CFR 606.160(b)(1)(vii)	Recordkeeping	Records to relate the donor with the unit number of each previous donation from that donor shall be maintained.
21 CFR 606.160(b)(1)(viii)	Recordkeeping	Records of quarantine, notification, testing, and disposition performed pursuant to §§ 610.46 and 610.47 shall be maintained.
21 CFR 610.46(a)	Reporting-Disclosure	Blood establishments shall notify consignees, within 72 hours, of repeatedly reactive tests results so that previously collected blood and blood components are appropriately quarantined.
21 CFR 610.46(b)	Reporting-Disclosure	Blood establishments shall notify consignees of licensed, more specific test results within 30 consecutive calendar days after the donor's repeatedly reactive test.
21 CFR 610.47(b)	Reporting-Disclosure	Transfusion services not subject to HCFA regulations shall notify physicians of prior donation receipients or recipients themselves, of the need for HIV testing and counseling.

Under the biologics licensing and quarantine provisions of the Public Health Service Act (42 U.S.C. 262 and 264) (Attachment B) and the general administrative provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351-353, 355-360, and 371-374) (Attachment C), FDA has the authority to promulgate regulations designed to protect the public from unsafe or ineffective biological products and to issue regulations necessary to prevent the introduction, transmission, or spread of communicable diseases.

FDA has implemented an extensive system of donor screening and testing procedures performed by blood establishments before, during, and after donation, to help prevent the transfusion of blood products that are at increased risk for transmitting HIV. HIV is the virus that causes acquired immune deficiency syndrome (AIDS), a communicable disease that can be transmitted through transfusion. Despite the best practices of blood establishments, however, a person may donate blood early in infection, during the period when the antibody to HIV is not detectable by a screening test, but HIV is present in the donor's blood (a so-called "window" period). If the donor attempts to donate blood at a later date, the test for antibody to HIV may, at

that time, be repeatedly reactive. Therefore, FDA believes such circumstances require clarification of the donor's status through testing with a more specific antibody test and procedures to "lookback" at prior collections.

FDA issued regulations (September 9, 1996, 61 FR 47413, Attachment D) that require blood establishments to follow written standard operating procedures (SOPs) when the blood establishments have collected Whole Blood, blood components, Source Plasma, and Source Leukocytes later determined to be at increased risk for transmitting HIV. When a donor who previously donated blood is tested on a later donation and tests repeatedly reactive for antibody to HIV, the regulations require blood establishments to perform more specific testing using a licensed test, and notify consignees who received Whole Blood, blood components, Source Plasma, and Source Leukocytes from prior collections so that appropriate action is taken. Blood establishments and consignees are required to quarantine previously collection Whole Blood, blood components, Source Plasma, and Source Leukocytes from such donors, and if appropriate, notify transfusion recipients. Upon completion of more specific testing, hospital transfusion services that do not participate in Medicare, and are therefore not subject to HCFA's regulations, are required to take steps to notify transfusion recipients, as appropriate. These regulations are intended to help ensure the continued safety of the blood supply by providing necessary information to users of blood and blood components and by providing appropriate notification of recipients of transfusion at increased risk for transmitting HIV infection.

2. Purpose and Use of the Information

FDA has taken steps to prevent the transmission of HIV infection through transfusion of blood and blood components by requiring that written SOPs be followed when prior collections are identified to be at increased risk for transmitting HIV. The recordkeeping requirements ensure that industry has the necessary information to perform the "lookback" procedures. The requirement for consignee notification ensures that the prior collections of blood and blood components are appropriately quarantined. The requirement for recipient notification provides an opportunity for counseling, appropriate testing, early treatment and precautions necessary to prevent further spread of the virus. In addition, the recordkeeping and reporting requirements ensure that industry collection of this information serves preventative and remedial purposes.

Without this information, FDA could not monitor industry procedures and discharge its statutory responsibility for protecting the nation's health.

3. Use of Information Technology and Burden Reduction

Establishments may use computer tapes or discs, microfiche or microfilm to record and store data and information rather than hard copy records if they choose. Notification of consignees can be accomplished by phone, fax, or mail. We are not aware of any other improved technology to reduce the burden.

4. Efforts to Identify Duplication and Use of Similar Information

This information is only required by FDA. No other agency requires similar information or data to be filed. This information is not available from any other source.

5. Impact on Small Businesses or Other Small Entities

FDA believes that the regulations should apply equally to all enterprises. While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses. CBER's Office of Communication, Training, and Manufacturers Assistance provides guidance to small businesses concerning regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

The requirement of less frequent information collection would not provide the information necessary for blood establishments to perform the "lookback" procedures, and for FDA to monitor the establishments procedures and assure the prevention of communicable disease. Records are reviewed at the time of inspection for compliance with FDA regulations and for any appropriate corrective action. Initial preparation of standard operating procedures is a one-time burden.

There are no technical or legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for the collection of the information requirements.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

In accordance with 5 CFR 1320.8(d), a 60-day notice for public comment on the information collection provisions was published in the **Federal Register** of August 3, 1999 (64 CFR 42132, Attachment E). No comments were received from the public.

9. Explanation of Any Payment or Gift to Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA is consistent with the Freedom of Information Act and the Agency's published regulations of "Public Information" under 21 CFR Part 20 which prohibit FDA from releasing to the public the names of patients, individual reporters, health care practitioners, hospitals, and any geographical identifiers.

11. Justification for Sensitive Questions

Questions of a sensitive nature are not applicable to this information collection.

12. Estimates of Hour Burden Including Annualized Hourly Costs

The estimated annual burden for this information collection is 80,926 hours.

Estimated Annual Reporting/Disclosure Burden					
21 CFR Section	No. Of Respondents	Annual Frequency per Response	Total Annual Response	Hours per Response	Total Hours

610.46(a)	3,076	60	184,560	0.17	31,375
610.46(b)	3,076	60	184,560	0.17	31,375
610.47(b)	180	16	2,880	0.5	1,440
Total					64,190

There are approximately 3,076 registered blood establishments that annually collect an estimated 24,000,000 units of Whole Blood and Source Plasma, and that are required to follow FDA "lookback" procedures. Of these establishments, approximately 180 are registered transfusion services that are not subject to HCFA's "lookback" regulations. The following reporting and recordkeeping estimates are based on information provided by industry, and FDA experience. It is estimated that an average of 60 repeat donors per establishment will test repeatedly reactive annually. This estimate results in a total number of 184,560 notifications of these test results to consignees by blood establishments for the purpose of quarantine of affected products, and another 184,560 notifications to consignees of subsequent test results. It is estimated that transfusion services not subject to HCFA regulations will need to notify physicians, or in some cases recipients, an average of 16 times per year resulting in a total number of 2,880 notifications. FDA estimates an average of 10 minutes per notification of consignees, physicians, and recipients. The estimate of one-half hour for § 610.47(b) is based on the minimum requirement of 3 attempts to notify recipients by transfusion services.

Estimated Annual Recordkeeping Burden					
21 CFR Section	No. Of Record-keepers	Annual Frequency of Recordkeeping	Total Annual Records	Annual Hours Per Recordkeeper	Total Record-keeping Hours
606.160(b)(1)(vii)	154	160	24,640	12.8	1,971
606.160(b)(1)(viii)	3,076	60	184,560	4.8	14,765
Total					16,736

The estimate of 154 recordkeepers and 160 records is based on the estimate that the requirement is already implemented voluntarily by more than 95 per cent of the facilities, which collect 98 percent of the Nation's blood supply. FDA estimates that it takes approximately 5 minutes to document and maintain the records to relate the donor with the unit number of each previous donation. The establishment of SOPs under § 606.100(b)(19) is a one-time burden. The burden associated with the maintenance of the SOPs is covered in 0910-0116.

Cost to Respondents

The estimated annualized cost to the respondents is $ 3,381088. This cost is based on a medical technologist (MT), at a pay rate of $ 27.63 per hour, who is responsible for recording donor, quarantine, testing, and disposition information, and notifying consignees of test results. The cost is also based on a supervisor, at a pay rate of $ 38.08 per hour, who is responsible for updating SOPs, recording donor information, and notifying physicians of recipients or recipients of test results, and a Medical Director (MD), at a pay rate of $ 59.63 per hour, who is responsible for updating SOPs and notifying physicians of recipients or recipients of test results. These salary estimates include recordkeeping and reporting-disclosure requirements are performed by the MT, supervisor, or MD, the cost per hour includes the average salary of the three ($41.78).

Cost to Respondents			
Activity	Number of Hours	Cost per Hour	Total Cost
Reporting	64,190	41,78	2,681,858
Recordkeeping	16,736	41.78	699,230
		TOTAL	3,381,088

13. Estimate of Other Total Annual Cost Burden to Respondents or Record-keepers

There are no capital and start-up, or operation, maintenance and purchase costs associated with the collection of information requirements.

14. Annualized Costs to the Federal Government

The estimated annual cost to the government is $195,264. This figure is based on a GS-12 Consumer Safety Officer, at a pay rate of $31.74, who performs on-site inspections. The estimate includes the estimated additional time required to inspect the facility and records associated with the 'lookback' requirements. The salary estimate includes benefits but no overhead costs.

Annual Cost to Federal Government				
Activity	Number of Respondents	Hours per Response	Cost per Hour	Total Cost
Inspection	3,076	2	$31.74	$195,264

15. Explanation of Program Changes or Adjustments

The estimated total annual burden for this information collection requirements was 85,528 hours in 1996. The current decrease to 80,926 burden hours is mostly attributable to the fulfillment for subsequent years on this one time requirement of preparation for SOPs under 21 CFR 606.100(b)(19), to review prior donations of blood and blood products from donors with no previous history of antibody to HIV who subsequently test repeatedly reactive for antibody to HIV.

The burden associated with the maintenance of the SOPs is covered in 0910-0116 (approved through February 23, 2001). Further change to this collection of information will occur as it will be consolidated with another package.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions to Item 19 of OMB Form 83-I.